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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Weenna Bucay-Couto

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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,231	Applicant(s) BUCAY-COUTO ET AL.	
	Examiner KATHERINE DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,21-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,21-23 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 13, 2010 has been entered.
2. Claims 1-19, 21-23, and 31 are currently pending. Claims 24-29 have been withdrawn from consideration.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-9, 11-19, 21-23, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (US 6,818,018) in view of Pathak et al. (US 2004/0023842, hereinafter "Pathak") and Weikel et al. (US 6,632,235, hereinafter "Weikel"). Regarding claims 1-8, 20, 21, and 31, Sawhney discloses the invention substantially as claimed including injecting a crosslinkable polymer (second fluid) and crosslinking agent to a target location within the body, such that the crosslinkable polymer is crosslinked in situ to form a solid or semisolid crosslinked polymer at the target location (col 6, ll 5-16; col 8, ll 25-29; col 18, ln 50 – col 19, ln 9; col 21, ll 44-58). Furthermore, a first fluid

comprising a non-crosslinkable polymer (release rate modification agent – col 18, ll 23-38) and a therapeutic agent (col 16, ln 10 – col 17, ln 65) is injected along with the crosslinkable polymer and crosslinking agent, such that the crosslinkable polymer coats the first fluid to form a solid crosslinked polymer containing the first fluid upon reaction of the crosslinkable polymer with the crosslinking agent (col 15, ln 66 – col 16, ln 2). However, Sawhney does not specifically disclose the first and second fluids are injected separately such that the first fluid is injected and then the second fluid is subsequently injected. Pathak discloses several biocompatible crosslinked polymers that may be polymerized in situ and teaches components of the polymer may be applied and mixed in situ using a double barrel syringe, wherein the solutions may be applied simultaneously or sequentially (¶0111). Therefore, it would have been prima facie obvious to try modifying the method of Sawhney first fluid was injected before the second fluid in an attempt to provide an improved method of forming the polymer in situ as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.

Sawhney discloses several polymer choices for both the non-crosslinkable polymer of the first fluid and the crosslinkable polymer of the second fluid (see above citations). It would have been prima facie obvious to try modifying the method of Sawhney to choose the materials such that the chosen crosslinkable polymer for the second material was less viscous than the chosen non-crosslinkable polymer for the first material to allow the second material to sufficiently coat the first material in an

attempt to provide an improved drug loaded hydrogel as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.

However, Sawhney discloses the fluids are directly injected into the target location and do not teach injecting the fluids and crosslinking agent into a container positioned within the target location. Wiekel discloses a similar method for forming a crosslinking a polymer in situ and teach the crosslinking agent and crosslinkable polymer are injected into a container (30) positioned within the subject (col 6, ll 5-13; col 10, ll 58-61; col 11, ll 27-37). By injecting the elements into a container placed within the subject, more controlled deployment of the crosslinked polymer may be obtained and the risk of polymeric precursors to other areas of the body is reduced (col 6, ll 5-13). The container is an expandable balloon, which may have elastic or inelastic walls (col 1, ll 58-60). Upon solidification of the polymer, the container may be removed to release the solidified polymer within the target area (col 6, ll 5-13; col 7, ll 16-25) or the container may be biodegradable and be released within the patient along with the solidified polymer (col 7, ll 26-43). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Sawhney such that first fluid, second fluid, and crosslinking agent were injected into a container placed within the target location as taught by Wiekel to ensure the first fluid, second fluid, and crosslinking agent do not migrate from the target location prior to solidification/crosslinking of the second fluid.

Regarding claim 9, the crosslinked polymeric body may be biodegradable (col 4, ll 52-55).

Regarding claims 11-19, the crosslinked polymeric body may be formed within a body cavity, a bodily lumen, at a surgically created site, within an aneurysm, or within a uterine fibroid tumor, wherein the crosslinked polymeric body may be an antiadhesive body, an embolic body, a bulking agent, or tissue scaffold (col 4, ll 56-61).

Regarding claims 22 and 23, an additional fluid comprising an additional crosslinkable polymer may be injected and crosslinked in situ to form a solid polymeric body comprising a plurality of polymers (col 10, ll 11-30).

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (US 6,818,018), Pathak (US 2004/0023842), and Weikel (US 6,632,235), as applied to claim 1 above, further in view of Spacek (US 6,524,327). Sawhney and Weikel disclose the invention substantially as claimed as shown above. However, they do not disclose the method comprises washing the crosslinked polymeric body prior to releasing the crosslinked solid polymeric body. Spacek discloses a method for forming a solid polymeric body in situ and teaches once the crosslinking, or bonding, is complete, the polymeric body should be washed to remove unreacted reactants and any byproducts to ensure biocompatibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Sawhney, Pathak, and Weikel such that the step of washing the solid

polymeric body was added to remove byproducts and reactants that may harm the body.

Response to Arguments

6. Applicant's arguments, see amendment, filed September 13, 2010, with respect to the rejection of the claims under Sawhney have been fully considered and are persuasive. Applicant argues Sawhney does not disclose injecting the first fluid and *subsequently* injecting the second fluid. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Pathak (US 2004/0023842).

7. Applicant additionally argues there is no reason to modify Sawhney to use a container as taught by Weikel to ensure the fluids taught by Sawhney do not migrate from the target location since Sawhney solved this problem in another way. The examiner respectfully disagrees. Contrary to Applicant's remarks, adding a container as described in Weikel would not change the principle of operation of Sawhney's invention. The compositions of Sawhney would still function to stabilize hydrogel-forming precursor solutions at the deposition site, now within the container, for a period of time sufficient for more resilient chemical crosslinks to form. The combination has the further advantage of ensuring any precursor solutions that may not be stabilized by the compositions of Sawhney do not migrate from the target location. Stated in another way, the container provides a second level of defense ensuring the precursor solutions do not migrate from the target location.

8. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine M Dowe/
Examiner, Art Unit 3734

July 5, 2011